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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,878	07/21/2003	John W. Goodin	GOODIN.002A	6792

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EXAMINER

GARBER, CHARLES D

ART UNIT PAPER NUMBER

2856

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/624,878

Applicant(s)

GOODIN, JOHN W.

Examiner

Charles D. Garber

Art Unit

2856

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-14 and 17 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 15, 16 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/29/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Pham (US Patent 6,616,893).

Regarding claim 1, Pham discloses a test kit including container vessel 14 which is a rigid outer substantially annular shell defining an open top, a bottom, an inside and an outside as shown in figure 1. Cup 12 is a substantially annular inner liner disposed within the vessel and having an open top, a bottom of side wall 18 having a passage 39 or 40 which is a flow aperture therein, an inside and an outside, the cup defining a sample chamber therein, the cooperation of the inside of the vessel and the outside of the cup defining a separation cavity 30 or test chamber as shown in figure 5 and 8. Cap 15 is a seal cap configured to seal the outer shell open top as shown in figure 1.

Pham further recites, "Should a test strip not be desired in one position, a plug such as a piece of tape could be placed over the aperture to remain sealed." The plugging tape is a plug configured to selectively fluidly seal the flow aperture in the cup as in the instant invention.

As for claim 3, see threads 37.

As for claim 8, see item 42, 57 in figures 1, 2 and 5.

Claims 9 and 10 are substantively the same as claim 3 as discussed above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pham (US Patent 6,616,893) in view of Levy (US Patent 6,361,744).

Pham lacks the cap having an access hole formed therein.

Levy teaches a urine container having a lid 14 with septum 18 for forming temporary openings through the lid.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide openings through the lid in a urine cup so that small

amounts may be drawn from the cup for various analysis procedures while preventing spillage or contamination of the sample (column 1 line 20 to column 2 line 9).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pham (US Patent 6,616,893) in view of Alley (US Patent 6,786,106)

Regarding claim 4, Pham does not teach the plug extending from the bottom of the vessel or outer shell inwardly such that it sealingly engages the hole or flow aperture.

Alley discloses a specimen cup for urine testing teaching probe 190 extending inwardly from the bottom of an outer vessel (shown generally in figure 13) for sealing the opening (item 22 shown in figure 8b) in an inner vessel defined by shaft 182, cone 184, closure 14 and plug/cover 70 (column 10 lines 17-53). Downward motion of the inner container within the outer container may selectively open or close the inlet 22.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a plug in the outer container that selectively opens or closes an inlet between the two vessels so that the sample may be selectively isolated or transferred between vessels by a simple upward or downward motion of one vessel with respect to the other.

As for claim 5, the probe or plug taught by Alley is configured to be displaced from a sealing engagement by manual displacement. It would have been obvious to one having ordinary skill in the art at the time the invention was made to do so for the same reason discussed above with respect to claim 4.

Claims 11-13 are substantively the same as claim 4 and claim 17 is substantively the same as claim 5 as discussed above.

As for claim 14, the tapered bottom 186 of Alley is considered a bottom cap configured to engage the plug and selectively displace the plug from the plug seat, thereby allowing fluid communication between the sample chamber and the test chamber. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the bottom cap for the same reason discussed above with respect to claim 4.

Allowable Subject Matter

Claims 6, 7, 15, 16, 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claims 6, the prior art does not disclose or suggest the plug further configured to be displaced from a sealing engagement by an interaction with a removable bottom cap.

Similarly, the prior art does not disclose or suggest the bottom cap being threadably engaged with the outer shell and is configured such that an unscrewing of the bottom cap from the outer shell displaces the plug from the plug seat as in claim 15.

Claim 16 depending from allowable claim 15 is allowable for the same reason.

As for claims 7 and 18, the prior art does not disclose or suggest the plug further configured to be displaced from a sealing engagement or from a plug seat by an external tool.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The additional references cited on the accompanying form PTO-892 though not cited above are provided to indicate other prior art sampling/testing vessels which include one or more features or limitations in common with the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles D. Garber whose telephone number is (571) 272-2194. The examiner can normally be reached on 6:30 a.m. to 3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

cdg



**CHARLES GARBER
PRIMARY EXAMINER**